REMARKS

Claims 1-27 were and remain pending, with claims 1-27 being amended herein.

Claims 1-27 were objected to because not all of the claims ended in a period. Further, claims 3-27 were objected to because they were improper multiple dependent claims.

Claims 2 and 26-27 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Claims 26-27 was also rejected under 35 U.S.C. § 101 as allegedly being in improper statutory form for a method claim.

In regard to prior art, claims 1-2 were each rejected under 35 U.S.C. § 102 as allegedly being anticipated by U.S. Patent No. 6,537,242 to Palmer, or, alternatively, U.S. Patent No. 4,953,552 to DeMarzo. Claims 3-27 were not analyzed, and thus not rejected, based upon the prior art due to their being considered by the Examiner to be improper multiple dependent claims.

Claim Amendments

All claims have been amended. Many have been amended to add a period, or to remove multiple dependencies. Thus, the objections raised in the Office Action have been obviated.

Further, claims 6-27 have been rewritten as method claims instead of use claims, making them fully in compliance with 35 U.S.C. § 101.

Claim 1 has been amended herein to clarify how the mechanism is releasable and thereby interacts with the surface to deform it into a convex shape and switch between the first and second position. Support for this amendment is found throughout Applicant's specification, including at, for example, paragraphs 0027-0030 of Applicant's published specification (U.S. Pat. App. Pub. No. 2008/0027296). As shown below, this amendment was not entered by Applicant to overcome the prior art rejections of record as those references failed to disclose a "surface" as presented in original claim 1, but rather have been voluntarily made to clarify Applicant's invention.

Claims 21 and 22 each have been amended similarly to make them dependent method claims reciting methods for using the device according to claim 1. The written description support for this amendment is found throughout Applicant's specification, including at, for example, paragraphs 0027- 0030 of Applicant's published specification. Again, these amendments are not being entered in response to any present rejection.

Applicant's Claimed Invention

Applicant's disclosed and claimed device is an implantable sensor that overcomes the problems associated with piercing and implanting the sensor (e.g., difficultly in implanting at the appropriate depth, pain, etc.). Applicant's disclosed and claimed device utilizes an active skin-insertion mechanism for implantable component of the sensor (e.g., a needle-type probe as depicted as element 9 in FIG. 1a) that controls the movement of the implantable component relative to the skin surface.

Traditionally, skin insertion of needle-type devices is effected either by manual piercing of the skin or by manual pressing a device holding the needle-type device fixedly against the skin. Manual insertion has several drawbacks, since the skin reacts elastically to pressure and therefore, especially for short needles and/or short implantation depths of the type usually present in skin sensor (e.g., a length/depth of only about 1-5 mm), a denting rather than a piercing of the skin might result. Palmer in particular discusses this problem, and describes how one can combat this tendency to just dent, rather than pierce, the skin by stretching the skin at the insertion site which reduces the skin's elastic denting tendency.

Because of the elastic reaction of the skin to pressure, another way to effectively pierce the skin is to have a high velocity of needle movement relative to the skin. This is not easily achievable with manual insertion, especially where there is a shallow insertion depth and/or if the needle is attached to the device and the entire device has to be moved against and/or attached to the skin. As taught in Applicant's specification, the claimed invention uses this approach and moves the skin surface relative to the implantable component of the sensor (e.g., a needle) at relatively high velocity in an automated manner controlled by a releasable mechanism. This mechanism is configured to be released after the sensor is attached (e.g., through an adhesive) to the skin surface, thus advantageously separating the step of attaching the sensor and implanting the sensor.

While other prior art technologies, such as Palmer and of DeMarzo cited by the Office Action, may address the problem of implanting a sensor in skin, none incorporate an insertion mechanism as disclosed and claimed by Applicant. Rather, as described below, they both use a conventional system whereby the act of manual pressing the device against the skin causes the skin piercing and implantation of sensors. In particular, Applicant's specification utilizes a

surface that adheres to the skin which is flexible such that it can be manipulated from a first position where the surface has a convex shape and where the implantable sensor (e.g., needle) is concealed behind the surface (see FIG. 3d and par. 0027) to a second position (see FIG. 1a and par. 0030) where the implantable sensor is exposed above the surface by the activation of a mechanism. The manipulation is automated by a mechanism that releases the surface from being restrained in the convex first position, allowing it to automatically adopt its second position (such as by springing action) to expose the sensor and thereby inject it the desired appropriate distance into the skin.

Thus, the devices according to the invention automate the acceleration of the skin (which is adhered to the surface) toward the implantable sensor by the release of the mechanism. Applicant has found that this type of sensor causes very little patient discomfort during implantation, and the device still is easy to attach accurately and securely (see par. 0027). Claims 21 through 27 describe methods for attaching and utilizing such sensors.

Claim Rejections under 35 U.S.C. §102 - Palmer:

Claims 1-2 were rejected for allegedly being anticipated by Palmer. Applicant respectfully traverses because Palmer fails to teach a device having every feature of the originally-filed claim 1. Specifically, Palmer fails to disclose a surface having the various characteristics recited in originally-filed claim 1, and furthermore fails to disclose a surface meeting the additional new features recited in claim 1 as currently amended herein.

Although Palmer generally pertains to the problem of implanting sensor components in skin, the disclosed construction and function of the Palmer device is significantly different and operates on a fundamentally different approach. Specifically, Palmer teaches that stretching the skin around location where the skin-penetrating microneedles will be inserted helps to combat dimpling and allow microneedle sensors to be implanted the appropriate depth (see, e.g., Palmer at col. 1 lines 56-67 and col. 3, lines 4-17). The Palmer device, upon manual downward pressure from the clinician, causes the skin to stretch outwardly while the microneedles are inserted by the pressure.

The Examiner contends that Palmer teaches a flexible surface that has, as originally claimed by Applicant, 1) a means for securing adherence to the surface of the skin, and 2) a first convex position concealing the implantable sensor and a second position where the sensor is

exposed above the surface. The Examiner also contends that Palmer teaches 3) a mechanism that deforms the surface to a convex shape and bends it from one to the other position. Palmer clearly does not teach these three elements.

First, the Examiner equates the four stretching member (66) arms, which each have bottom ends (62), as comprising a flexible surface as recited in original claim 1. While each Palmer stretching member may be flexible and may comprise or define various different surfaces, clearly nowhere does Palmer show a single surface where:

- the surface has means for adherence to the surface of skin (such as the adhesive layer 6 used in preferred embodiments of Applicant's invention disclosed in the specification),
- the surface has a first position that conceals an implantable sensor,
- the surface has a second position where the sensor extends above the surface, and
- a mechanism that deforms the surface to a convex shape and bends the surface from one position to the other position.

The Examiner clearly makes the error of pointing to different elements of Palmer for each claim limitation above, without regard that Applicant's claim required these to be present for the same surface. Contact between the Palmer device and the skin occurs at edge (62) of each stretching member. Nowhere does Palmer teach that these stretching members (66) have an adhesive anywhere on them, nor that they have any other means whatsoever for securing to the skin. Further, and most importantly, nowhere does Palmer teach any single flexible surface, whether defined by stretching members (66) and edges (62) or otherwise, is both deformed to a convex shape and has a means for securing adherence, as originally claimed. Second, the Examiner points to the undulating surface between the microneedles in FIG. 9 as comprising a convex shape – completely ignoring that the flexible surface must have this convex shape. That undulating shape between the microneedles cannot comprise the surface as originally claimed in claim 1 – there is no indication that it is flexible, and no indication that it ever conceals the microneedles. Thus, the Examiner is pointing to various different and unrelated parts of Palmer's device (the stretching elements and the undulating surface holding the microneedles) to satisfy the various different elements of the surface recited in Applicant's claims. Thus, original claim 1 was not anticipated by Palmer.

Claim 1 as currently amended also further distinguishes over Palmer. Specifically, claim 1 now requires "a releasable mechanism that when locked deforms the surface to a convex shape in the first position and when released causes the surface to adopt the second position." Reading this limitation with the balance of claim 1, Applicant's claimed invention now further requires that this surface is deformed into a convex shape in the first position by a releasable mechanism, that this convex shaped first position conceals the sensors, and that the mechanism when released causes the surface to adopt the second position where the sensors are exposed above the surface. The Examiner points to FIG. 9 of Palmer as allegedly showing a convex shape for the stretching members (66). However, when the stretching members are in that position, it is clear that the microneedles 43' become exposed. Further, in no way can FIG. 9 be characterized as showing the microneedles being concealed behind a convex flexible surface.

Palmer also fails to teach a releasable mechanism that when locked deforms the surface into the convex shaped first position and when released causes the flexible surface to adopt the second position where the implantable sensor is exposed above the surface. Physical pressing down on the Palmer device causes the stretching members to move outward and allows the microneedles to be inserted into the skin – there is no releasable mechanism as claimed in claim 1 present anywhere in Palmer. Thus, claim 1, and all claims dependent therefrom, are further patentable over Palmer for these additional reasons.

In this regard, Palmer does not anticipate or render obvious original claim 1, as-amended claim 1, or any claim dependent therefrom. Removal of this rejection is thus required.

Claim Rejections under 35 U.S.C. §102 – DeMarzo:

Claims 1-2 were also rejected for allegedly being anticipated by DeMarzo. Applicant respectfully traverses because DeMarzo likewise fails to teach a device having every feature of the originally-filed claim 1. Specifically, Demarzo fails to disclose a surface having the various characteristics recited in originally-filed claim 1, and likewise fails to disclose a surface meeting the additional new features recited in claim 1 as currently amended herein.

DeMarzo in particular does not teach about an active skin-insertion mechanism. Insertion of the sensor elements into the skin is achieved in DeMarzo by manual pressing of the device with fixedly attached electrode needles against the skin (Col 6 lines 4-6). The Examiner argues that DeMarzo teaches means (element 38, Fig 4) to position a flexible surface relative to

the sensors in such a way that in the first position way that in a first position the sensors are concealed by the surface (needle tip 60 is sealed by element 38, as shown in DeMarzo Fig 4) and in a second position the implantable parts of the sensors (needle tip 64, Fig 4) are exposed above the surface (element 38 is removed and the needle is inserted into the skin, Fig. 4). Again, the Examiner improperly is swapping his definition of which elements of DeMarzo serve as the flexible surface in order to ostensibly satisfy every element of original claim 1.

Specifically, the Examiner appears to be forgetting that the device claimed by Applicant has means for securing adherence of the flexible surface to the skin. The Examiner defines element 38 of DeMarzo, a disposable peelable release sheet that covers the adhesive coating 36 of the patch before application onto the patient, as the flexible surface. In conventional fashion, this sheet it is peeled off before use (Col 3 lines 12-16) and discarded while the adhesive stays on the device. Thus, given what Examiner identifies as the surface, in no way can DeMarzo be characterized as disclosing a device that has a "means for securing adherence of that surface to the skin," or a flexible surface that has a position where the sensor is "exposed above the surface" as originally claimed.

Furthermore, original claim 1 required a mechanism to deform the surface to a convex shape and to bend it from one to the other position. For this element in DeMarzo, the Examiner points to element 58 of Fig. 4, a flared end surrounding the needle electrode, and argues that it will deform the surface of the skin to a curved shape. Applicant does not contest that the flared end will bend the shape of the skin when the DeMarzo device is pressed against the skin. However, even if this flared end 58 does operate as alleged, it still does not qualify as a mechanism as recited in original claim 1. In particular, the flared end 58 does not in any way bend the surface from the one to the other position as required by Applicant's original claim 1. What bends the surface (i.e., peelable sheet 38) in Demarzo from the two positions is the manual act of a doctor or other person simply peeling off the sheet with his or her fingers. Clearly, the device of DeMarzo contains no mechanism for changing the position of a flexible surface. Thus, the Examiner is pointing to various different and unrelated parts of Palmer's device (the stretching elements and the undulating surface holding the microneedles) to satisfy the various different elements of the surface recited in Applicant's claims. Thus, original claim 1 was not anticipated by DeMarzo.

Claim 1 as currently amended also distinguishes over DeMarzo for additional reasons.

As described above with respect to Palmer, claim as amended requires "a releasable mechanism that when locked deforms the surface to a convex shape in the first position and when released causes the surface to adopt the second position." Thus, claim 1 as now amended requires that the surface is deformed into a convex shape in the first position by a releasable mechanism, that this convex shaped first position conceals the sensors, and that the mechanism when released causes the surface to adopt the second position where the sensors are exposed above the surface. Nowhere does DeMarzo describe such a releasable mechanism for locking the implantable sensor in a concealed position behind a convex surface and then releasing the mechanism to cause the implantable sensor to be exposed above the surface. Instead, DeMarzo relies upon physical removal of the peel-away sheet by a user to expose the sensor. In no way could a physical action required by a person be characterized as a physical element of a device. Thus, claim 1, and all claims dependent therefrom, are further patentable over Palmer for these additional reasons.

Appropriate reconsideration of all prior art rejections is thus requested.

A second action "Final" would be improper

Although Applicant has amended all claims herein, it would be improper for the Examiner to designate any second Office Action as a "Final" rejection. As noted above, the original, un-amended language remaining in the present claims distinguish over all prior art rejections of record. The Examiner would be required to introduce new references to reject Applicant's claims based upon prior art even if Applicant had not made the amendments herein. Thus, any new prior art rejections raised by the Examiner could not be characterized properly as being necessitated by Applicant's amendment.

CONCLUSION

In view of the foregoing, the Applicants respectfully request that the Examiner consider the claims on the merits. A timely allowance of the pending claims is requested.

If there are any fees due in connection with the filing of this Response, please charge any necessary fees or credit any overpayments to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicants' undersigned attorneys by telephone to discuss any matters if the Examiner feels such discussions may expedite the progress of the present application toward allowance.

Respectfully submitted,

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